AMENDMENTS TO THE CLAIMS

1. (currently amended) A pharmaceutical composition comprising:

a therapeutically effective amount of a drug;

a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid monoglycerides, caprylic acid diglycerides, and monoacetylated monoglycerides and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α-tocopherol, α-tocopherol acetate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate, α-tocopherol polyethylene glycol 400 succinate, d1-α-tocopherol polyethyleneglycol 1000 succinate, and d-α-tocopherol polyethyleneglycol 1000 succinate~~;

and a release modulator which synchronizes the release of the drug and the solubilizer, wherein the release modulator is selected from the group consisting of methyl cellulose, a hydroxypropyl methylcellulose, hydroxypropyl methyl cellulose phthalate, hydroxymethylcellulose succinate, ethyl cellulose, an acrylic polymer, a polyvinylpyrrolidone copolymer, a polyvinyl acetyl phthalate, acacia, xanthan gum, tragacanth, shellac, hydrogenated vegetable oil, glycerol dibehenate, glycerol dipalmitate, glycerol palmitostearate, glycerol distearate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate~~, sucrose distearate, cetyl ester wax, and mixtures thereof

wherein the composition is formulated to release the drug over an extended period of time, said extended period of time being between 2 and 24 hours.

2. (previously presented) The pharmaceutical composition of claim 1, wherein the drug is pioglitazone, zafirlukast, simvastatin, atorvastin or fenofibrate.

3-12. (canceled)

13. (previously presented) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is about 100 μg/ml or less.

14. (previously presented) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is about 50 μg/ml or less.

15. (previously presented) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is about 25 μg/ml or less.

16-19. (canceled)

20. (original) The pharmaceutical composition of claim 1, wherein the solubilizer increases the solubility of the drug by at least 25% in comparison to the intrinsic aqueous solubility of the drug.

21. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.80.

22. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.90.

23. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.95.

24. (original) The pharmaceutical composition of claim 1 including one or more additives.

25-28. (canceled)

29. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is dependent on pH.

30. (previously presented) The pharmaceutical composition of claim 29, wherein the drug has a pK_a of about 9.0 or less.

31. (previously presented) The pharmaceutical composition of claim 30, wherein the drug is carvedilol, amiodarone, dronederone, risperdone, topiramate, nimodipine or ziprasidone.

32. (currently amended) A oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid mono_glycerides, caprylic acid [/]diglycerides, and monoacetylated monoglycerides[-], and mono- and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α-tocopherol, α-tocopherol acetate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate, α-tocopherol polyethylene glycol 400 succinate, d1-α-tocopherol polyethyleneglycol 1000 succinate, and d-α-tocopherol polyethyleneglycol 1000 succinate~~;

and a release modulator which synchronizes the release of the drug and the solubilizer, wherein the release modulator is selected from the group consisting of methyl cellulose, a hydroxypropyl methylcellulose, hydroxypropyl methyl cellulose phthalate, hydroxymethylcellulose succinate, ethyl cellulose, an acrylic polymer, a polyvinylpyrrolidone copolymer, a polyvinyl acetyl phthalate, acacia, xanthan gum, tragacanth, shellac, hydrogenated vegetable oil, glycerol dibehenate, glycerol dipalmitate, glycerol palmitostearate, glycerol distearate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate~~, sucrose distearate, cetyl ester wax, and mixtures thereof

wherein the composition is formulated to release the drug over an extended period of time, said extended period of time being between 2 and 24 hours.

33. (currently amended) A solid oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35

castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid mono glycerides, caprylic acid [/]diglycerides, and monoacetylated monoglycerides[-], and mono- and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α-tocopherol, α-tocopherol acetate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate, α-tocopherol polyethylene glycol 400 succinate, d1-α-tocopherol polyethyleneglycol 1000 succinate, and d-α-tocopherol polyethyleneglycol 1000 succinate~~;

and a release modulator which synchronizes the release of the drug and the solubilizer, wherein the release modulator is selected from the group consisting of methyl cellulose, a hydroxypropyl methylcellulose, hydroxypropyl methyl cellulose phthalate, hydroxymethylcellulose succinate, ethyl cellulose, an acrylic polymer, a polyvinylpyrrolidone copolymer, a polyvinyl acetyl phthalate, acacia, xanthan gum, tragacanth, hydrogenated vegetable oil, glycerol dibehenate, glycerol dipalmitate, glycerol palmitostearate, glycerol distearate, α-tocopherol succinate, ~~α-tocopherol polyethyleneglycol succinate~~, sucrose distearate, cetyl ester wax, and mixtures thereof

wherein the composition is formulated to release the drug over an extended period of time, said extended period of time being between 2 and 24 hours.

34-37. (canceled)

38. (previously presented) The pharmaceutical composition of claim 1, wherein the release modulator is a polyvinylpyrrolidone copolymer.

39. (previously presented) The pharmaceutical composition of claim 38, wherein the polyvinylpyrrolidone copolymer is a polyvinylpyrrolidone-vinyl acetate copolymer.

40-41. (canceled)

42-43. (canceled)

44. (withdrawn) A method of synchronizing the release of a drug and a solubilizer comprising:

co-administering a release modulator with a formulation including the drug and the solubilizer.

45. (withdrawn) The method of claim 44, wherein the solubilizer is selected from the group consisting of selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid mono/diglycerides, and mono- and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α-tocopherol, α-tocopherol acetate, α-tocopherol succinate, α-tocopherol polyethyleneglycol (200-8000 MW) succinate, α-tocopherol polyethylene glycol 400 succinate, d1-α-tocopherol polyethyleneglycol 1000 succinate, and d-α-tocopherol polyethyleneglycol 1000 succinate.

46. (withdrawn) The method of claim 44, wherein the drug is pioglitazone, zafirlukast, simivastatin, atorvastin or fenofibrate.

47. (withdrawn) The method of claim 44, wherein the drug has an aqueous solubility of less than about 100 μg/ml.

48. (withdrawn) The method of claim 44, wherein the drug has an aqueous solubility of less than about 50 μg/ml.

49. (withdrawn) The method of claim 44, wherein the drug has an aqueous solubility of less than about 25 μg/ml.

50. (withdrawn) The method of claim 44, wherein the synchronized release of the drug and the solubilizer is over an extended period of time.

51. (withdrawn) The method of claim 50, wherein the extended period of time is from about 2 hours to about 24 hours.

52. (withdrawn) The method of claim 44, wherein the solubilizer increases the solubility of the drug by at least 25% in comparison to the intrinsic aqueous solubility of the drug.

53. (withdrawn) The method of claim 44, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.80.

54. (withdrawn) The method of claim 44, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.90.

55. (withdrawn) The method of claim 44, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.95.

56. (withdrawn) The method of claim 44, wherein the aqueous solubility of the drug is dependent on pH.

57. (withdrawn) The method of claim 56, wherein the drug has a pK_a of about 9.0 or less.

58. (withdrawn) The pharmaceutical composition of claim 44, wherein the drug is carvedilol, amiodoarone, dronederone, risperdone, or ziprasidone.

59. (withdrawn) The method of claim 44, wherein the release modulator is selected from the group consisting of polyvinyl acetyl phthalate, an acrylic polymer a high molecular weight polysaccharide gum, glycerol dibehenate, glycerol stearate, α-tocopherol succinate; α-tocopherol polyethylene glycol succinate, cetyl ester wax, or mixtures thereof.

60. (withdrawn) The method of claim 44, wherein the release modulator is a polyvinylpyrrolidone copolymer.

61. (withdrawn) The method of claim 60, wherein the polyvinylpyrrolidone copolymer is a polyvinylpyrrolidone-vinyl acetate copolymer.

62. (withdrawn) The method of claim 44, wherein the release modulator a selected from the group consisting of a acrylic polymer, a shellac, a polyvinyl acetyl phthalate, a polysaccharide gum, or mixtures thereof.

63. (withdrawn) The method of claim 44, wherein the release modulator is glycerol dibehenate, glycerol distearate, glycerol dipalmitate, glycerol palmitostearate, stearoyl macrogol-32 glyceride, calcium steroyl lactylate, stearoyl alcohol, yellow wax, white wax, nonionic emulsifying wax, carnauba wax, microcrystalline wax, cetyl ester wax or mixtures thereof.

64. (withdrawn) The method of claim 44, wherein the solubilizer is d-α-tocopherol polyethylene glycol 1000 succinate and the release modulator is α-tocopherol succinate, glycerol dibehenate or hydroxypropylmethylcellulose.

65. (withdrawn) The method of claim 64, wherein the solubilizer is d-α-tocopherol polyethylene glycol 1000 succinate, the release modulator is α-tocopherol succinate.